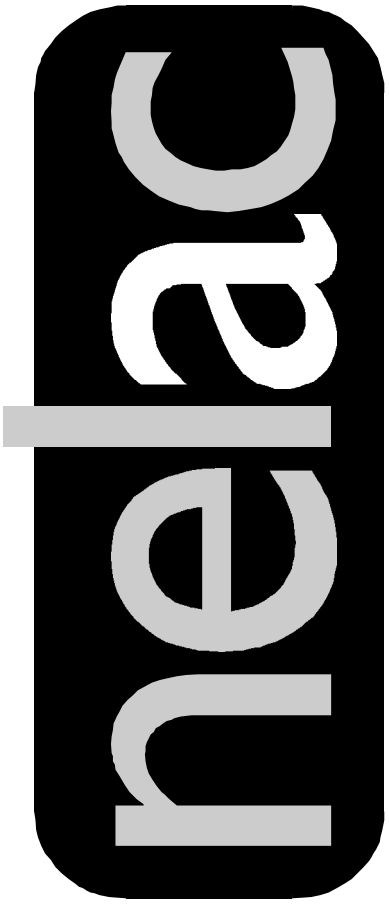
National Environmental Laboratory **Accreditation** Conference



Proficiency Testing

Proposed Changes

January 12, 1998

2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

For the period beginning with adoption of these standards by NELAC and ending September 30, 1998, all NELAP-approved primary accrediting authorities shall accept data from proficiency testing programs that meet the requirements of . . . . .

~~Accrediting~~Primary accrediting authorities may rely on the current laboratory performance evaluation studies conducted by EPA. These include: the Water Supply (WS) Study, conducted twice annually; the Water Pollution (WP) study, conducted twice annually; and the Discharge Monitoring Report Quality Assurance (DMRQA), conducted once annually. Alternatively, primary accrediting authorities may rely on other sources for performance evaluation studies (such as . . . . .

2.1 INTRODUCTION, SCOPE, AND APPLICABILITY

This chapter and the associated appendices define the major participating organizations and components of the NELAC . . .
standard are considered to be default requirements, and shall be used in the absence of specific EPA program ~~criteria~~ regulations. If they conflict with any documented EPA program ~~criteria~~ regulations, the program ~~criteria~~ regulations shall have precedence.

Proficiency Testing (PT) is defined for the purpose of this . . . . .
determining accreditation status. Additional essential elements of the overall NELAC accreditation process, including the ~~laboratory audit~~ on-site assessment, are discussed in other chapters of the NELAC standards. . . . . .

2.1.1 Purpose

The PT program incorporates several practical purposes, which include:
. . . . .
b) . . . . .
possible. It is further expected that the PT samples will be representative of materials analyzed for environmental regulatory programs, agencies, and communities;

e) . . . .
for analysis by a Drinking Water or Wastewater method would pose equal challenge whether prepared as whole volume or ~~concentrated~~ as a concentrate in ampules.

2.1.3 PT fields of testing

The PT program is organized by PT fields of testing.
. . . .
define PT fields of testing:

a) Regulatory or environmental program, as listed in Chapter 1,

b) Matrix type (e.g. gas, aqueous liquid, nonaqueous liquid, solid), and

2.2 MAJOR PT GROUPS AND THEIR RESPONSIBILITIES

The PT program structure incorporates five major groups with separate and distinct roles and responsibilities. The groups are NELAC, the Proficiency Testing Oversight Body (PTOB), the PT Providers, the testing laboratories, and the primary Accrediting Authorities (AA).

2.2.1 NELAC and NELAP

~~NELAP is the Standards Setting Authority (SSA) which is responsible for administering the~~ NELAC is the Standards Setting Authority (SSA) which is responsible for administering the NELAP PT program. . . . .

2.2.2 PT Study Providers

The providers shall produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to the laboratories, the respective primary Accrediting Authorities, ...

2.2.4 Laboratories

Laboratories that seek to become accredited ~~by NELAP~~ shall perform analyses . . . .

2.2.5 Accrediting Authorities (AA)

~~The States or the EPA Regions which hold primary Accrediting Authority are the Accrediting Authorities for those laboratories located within their respective boundaries.~~ The primary accrediting authorities shall make all decisions regarding a laboratory's accreditation status. They are responsible for taking action to make these determinations including ensuring that laboratories seeking or holding their accreditations are participating in the PT program.

2.3.2.1 Sample Analytes

The PT Provider shall prepare each sample lot such that the target concentration of each analyte in each lot is unique. The required group of analytes in each sample covering each field of testing shall be determined by NELAC and shall be evaluated and updated annually, as necessary. ~~For a given field of testing, it is not necessary that every analyte be present in every study.~~ Within each study, a certain minimum number of analytes shall be present. The group of analytes included shall change over time so that all analytes are ~~eventually~~ included at least once every three years over a series of sequential studies.

2.3.6 Disapproval of PT Study Providers

A PT Provider's approval may be subjected to revocation per the procedures outlined in Appendix A, Section A.9.2 ~~shall be disapproved if documented deviations from the standard identified by the AA, the PTOB, or participating laboratories are not resolved within 30 calendar days after the provider is notified in writing of the problem (Refer to Appendix A)~~.

2.4 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

2.4.1 Required Level of Participation

To be accredited initially and to maintain accreditation, each laboratory shall participate in a PT study provided by a PTOB Approved PT Provider. Laboratories must request accreditation for a field of testing, as described in ~~Section 2.1.4 of this~~ Chapter 1. Each laboratory . . . .

2.4.2 Requesting Accreditation

At the time each laboratory applies for accreditation, it shall notify the accrediting authority which field of testing ~~that~~ it chooses to complete to meet PT requirements. For all fields of testing, including those ~~tests~~ for which PT samples . . . .

2.5 REQUIREMENTS FOR LABORATORY TESTING OF PT STUDY SAMPLES

A laboratory must participate in two ~~PTOB-approved~~ single-blind, single-concentration PT studies provided by a PTOB-approved PT provider per year for each field of testing for which it seeks or wants to maintain accreditation. The samples shall be analyzed and the results returned to the PT study provider no later than ~~30~~ 45 calendar days from ~~the date of sample receipt~~ the scheduled study shipment date. The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples ~~to the extent possible. The laboratory shall utilize the same staff, procedures, equipment, facilities, and frequency of analysis for PT samples as for real environmental samples~~ utilizing the same staff, methods, procedures, equipment, facilities, and frequency of analysis.

2.6 EVALUATION OF PROFICIENCY TESTING RESULTS

~~Program specific criteria apply where available, but in the absence of specific criteria established by the appropriate EPA program offices the criteria presented in this section and associated Appendix C are considered to be NELAC defaults that would apply.~~

~~2.6.1 Scoring of Laboratory PT Sample Results~~

PT study providers shall evaluate results from all PT studies using NELAC-mandated acceptance criteria ~~as~~ described in Appendix C. NELAC shall provide, ~~(~~ and update on an annual basis ~~)~~, the data acceptance criteria that all PT study providers shall use for all PT ~~study data~~ studies. Each result will be scored on an acceptable/not acceptable basis. The PT study provider will provide the participant laboratories and the primary ~~the~~ accrediting authority~~, the PTOB, and NELAP~~ a report showing at least the ~~target~~

assigned value, the acceptance range, and the acceptable/not acceptable status for each analyte ~~for each~~ reported by the laboratory ~~participant~~. The report shall be sent no later than 21 calender days from the study closing date. The providers shall not disclose specific laboratory results or evaluations to any other parties not described in this section.

2.7 PT CRITERIA FOR LABORATORY ACCREDITATION

The criteria presented in this section and associated Appendix C are considered to be NELAC defaults that would apply in the absence of specific ~~criteria~~ program regulations established by the appropriate EPA program offices. ~~The various EPA program offices may choose to establish their own program-specific criteria.~~

2.7.2 Initial and Continuing Accreditation

A laboratory ~~which~~ seek~~s~~ing accreditation shall successfully complete two PT studies for each requested field of testing within the most recent three rounds attempted. Successful performance is described in Appendix C. Once a laboratory has been granted accreditation status, it must continue to complete PT studies and maintain a history of at least two ~~successful~~ acceptable studies out of the most recent three. For either initial or continuing accreditation, . . .

2.7.3 Supplemental Studies

A laboratory may elect to ~~conduct~~ participate in PT studies more frequently than required . . . .

2.7.5 Second Failed Study

The PT Provider reports laboratory PT performance results to the accrediting authority at the same time that it reports the results to the laboratory. If a laboratory fails a second study out of the most recent three, as described above, the accrediting authority shall take action within 60 days to determine the capability of the laboratory to meet accreditation requirements. The primary accrediting authority shall review the accreditation status of all methods ~~related to the~~ for the unacceptable analyte(s). ~~in the failed study, and not just the method by which the failed PT was analyzed.~~

APPENDIX A

PT PROVIDER APPROVAL CRITERIA

A.2.0 QUALITY SYSTEM REQUIREMENTS

The manufacturing quality system used by the PT Provider must meet the requirements of both ISO 9001 for the design, ...
required in Appendix B of this document must meet the requirements of both ISO Guide 25 General Requirements for the Competency of Testing and Calibration Laboratories and Chapter 5, Quality Systems, of the NELAC standards. ~~for the quality of testing facilities.~~ The ability to meet the ISO 9001 quality system requirement may be fulfilled through registration of the PT Provider's quality system to~~by an~~ ANSI standards by an RAB accredited registrar. However, a~~n~~ biannual on-site inspection by the PTOB demonstrating continuing conformance~~performance~~ is required.

A.3.0 PROVIDER FACILITIES AND PERSONNEL

Each Provider is required to have systems in place to produce, . . .
since it is essential that the confidentiality of the samples be maintained throughout the PT study. For the purposes of this requirement "control" can mean ownership or that the subcontracted service is performed under an agreement which specifically ensures the ability of the Provider to access and restrict the distribution of information related to these services.

A.4.0 SAMPLE ~~DESIGN~~FORMULATION REVIEW

The PT Provider must demonstrate to the PTOB, by the submission of appropriate data, that the sample ~~design~~formulation for which the PT Provider is seeking approval will permit participating laboratories to generate results that fall within the sample acceptance ranges established by NELAC or the PTOB and meet the criteria of the National Standards for Proficiency Testing.

A.4.1 RELEASE OF INFORMATION

In support of the above requirement, the PTOB agrees to treat all sample ~~design~~formulation information submitted to them for review as the proprietary information of the PT Provider submitting the information. Such ~~design~~formulation information shall not be released by the PTOB without the prior written consent of the PT Provider.

A.5.0 PROVIDER CONFLICT-OF-INTEREST REQUIREMENTS

. . . .
disclosure to the PTOB. The disclosure shall include a description of any action which the Provider has taken or proposes to take, after consultation with the PTOB, to

A.5.1 BAN ON DISTRIBUTION OF SAMPLES

~~Furthermore, PT~~ Providers shall not sell, distribute, or provide samples used in the NELAC PT program prior to the conclusion of the study for which they were designed. Providers further agree not to sell, distribute, or provide samples of identical ~~design~~formulation and concentration to those samples which it is currently using in a NELAC study.

A.6.0 CONFIDENTIALITY OF PT STUDY DATA

The PT Provider shall demonstrate to the PTOB that is has systems in place to ensure that the confidentiality of data associated with NELAC PT samples and programs is not compromised. PT Providers shall not release the ~~Target~~Assigned Value of any sample currently being used in a NELAC PT study prior to the conclusion of the study. The PT Provider also agrees that the acceptance ranges provided to them by either NELAC, or the PTOB, are the proprietary information of NELAC, or the PTOB, and shall not be disclosed by the PT Provider without the written approval of the PTOB.

A.7.0 DATA REVIEW AND EVALUATION

The NELAP a~~A~~pproved PTOB will review the data from every PT Provider's studies~~y~~ to ensure that acceptance limits used to evaluate laboratories are consistent with national standards as established by NELAC. The PTOB will also evaluate the performance of the PT Providers by monitoring and reporting,

to both the Providers and NELAC the pass/fail rates of all Providers on all samples tested. The PTOB is required to investigate any PT Provider whose pass/fail rate is statistically different from the national average.

A.8.0 COMPLAINTS & CORRECTIVE ACTION

Written complaints received by the PT Provider regarding technical or procedural aspects of the studies they conducttheir performance in the NELAP PT program must be submitted to the PTOB within seven days from receipt of the complaint by the PT Provider. The PT Provider shall resolve the complaint to the satisfaction of the PTOB within 30 days from the date received by the PTOB. The PTOB is the sole judge of the adequacy of the corrective action taken by the PT Provider. It is the responsibility of Tthe PTOB willto provide NELAP with an annual summary of all PT Provider complaints received during the prior year.

A.9.0 LOSS OF PROVIDER APPROVAL

PT Providers who fail to meet the requirements of these standardsis appendix or those of Appendix B, may be subject to loss of their approval as a NELAC PT Provider. Providers may lose approval to provide individual sample sets based upon review of PT study data by the PTOB as required in Appendix A Section A.7. Similarly, PT Providers who fail to meet the requirements of Appendix A, Sections A2 through A6, on a continuous basis may lose their approval as a PTOB aApproved PT Provider for all samples.

A.9.1 PERIODIC REVIEW OF PT PROVIDERS

The PTOB may at any time, review the performance of any approved PT Provider against these standards terms and conditions of both Appendix A and Appendix B. Based upon this review, the PTOB may decidedetermine that the approval status of a PT Provider be revoked, adjusted, limited, or otherwise changed based upon failure to meet one or more of the specified requirements.

APPENDIX B

PT SAMPLE DESIGN & ACCEPTANCE GUIDELINES

B.3.0 STABILITY TESTING

The samples used in the NELAC PT program must ~~to~~ be verified as stable for the period of each study. Therefore, the .

APPENDIX C

PROFICIENCY TESTING ACCEPTANCE CRITERIA AND PROFICIENCY TESTING PASS/FAIL CRITERIA

C.0.0 PURPOSE, SCOPE, AND APPLICABILITY

This Appendix defines the criteria to be used by any entity which seeks to participate as a Proficiency Test Provider in . . . .
laboratory's NELAP accreditation status. PT acceptance limits and pass/fail criteria are established on a Program-matrix-analyte basis ~~according to PT fields of testing, which are defined in Chapter 2 of the NELAC standards~~.

C.1.1 ANALYTE ACCEPTANCE LIMIT CATEGORIES

Acceptance limits are separated into three categories. Results for analytes with acceptance limits determined as described in Sections C.1.1.1 and C.1.1.2 will be used in the determination of a laboratory's Program-matrix-analyte ~~PT Field of Testing~~ pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section C.1.1.3 will not be used as part of the ~~PT Field of Testing~~ Program-matrix-analyte pass/fail evaluation.

C.1.1.2 Analytes with acceptance limits derived from regression equations established by the PTOB ~~and approved by the NELAC~~

When EPA Program regulation or guidance for establishing acceptance criteria are not available Proficiency Test . . . .
proficiency testing providers, commercial and non-profit organizations, will be used to establish the equations. All regression equations will be approved by the PTOB ~~NELAC~~ prior to use by a PTOB Approved PT provider. For these analytes, the PT Provider shall use the sample's validated target value and said equations to determine the mean and standard deviation. ~~The regression equations shall be designed to be applicable across the NELAC designated PT concentration range.~~

C.1.1.3 Analytes without promulgated acceptance limits or EPA established regression equations, i.e., "Experimental Data"

For those analytes not included in categories C.1.1.1 or C.1.1.2, e.g., newly regulated analytes, or analytes in a
. . . .
the one-year period shall be referred to as "experimental data". ~~NELAC with the assistance of t~~The Proficiency Testing Oversight Body, will derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected. The laboratory will receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

C.3.0 "NOT ACCEPTABLE" PT RESULTS FOR POTABLE WATER, NON-POTABLE WATER AND HAZARDOUS WASTE PT SAMPLES

A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

. . . .
c) The lab reports a result of "Not Detected", (or similar indication of no detection), for an analyte present in the PT sample (i.e., a false negative);

C.4.0 ADDITIONAL REQUIREMENTS FOR PT PROVIDERS

PT Providers shall examine all data sets for bimodal distribution and/or situations where results from a given
. . . .
reviewed annually by the NELAC Standing Committee for Proficiency Testing in conjunction with the EPA and the PTOB for the purpose of revising existing and establishing new linear regression equations.

C.5.3 PROMULGATED EPA PASS/FAIL CRITERIA

In all cases, promulgated EPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), will be used as NELAC PT pass/fail criteria as applicable. The criteria described in ~~the~~

~~following~~ Section~~s,~~ 5.4 ~~and 5.5,~~ shall be used in the absence of promulgated EPA pass/fail guidelines.

~~C.5.5 PASS/FAIL CRITERIA FOR NON-INTERDEPENDENT ANALYTE PT SAMPLES~~

~~To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for all analytes in a Non-Interdependent Analyte PT Sample. One or more "Not Acceptable" results will result in the laboratory receiving a score of "Fail" for that Field of Testing sample.~~

APPENDIX D

PROFICIENCY TESTING OVERSIGHT BODY

D.1.0 TECHNICAL AND ADMINISTRATIVE QUALIFICATIONS

The PTOB shall demonstrate to ~~NELAP~~ NELAC by the submission of a current Statement of Qualifications that it has the technical expertise, administrative capacity, and financial . . . .

D.2.3 Final Report Submittal NELAP and the PT Provider

No later than ninety (90) days after the completion date of inspection, the PTOB shall submit to NELAP and to the Provider a final report that includes the PTOB's final inspection report, the Provider's response to the inspection report, and the review of the initial application with associated documents. The report shall also include the PTOB's determination of whether the PT Provider is approved to provide NELAC samples. As part of the initial application process, the PT Provider will sign a waiver permitting the PTOB to release to NELAP non-confidential business information as necessary in the final report.